UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,084	02/08/2002	Jose V. Torres	3648.032	9437

41288 7590 01/10/2005

PENDORF & CUTLIFF
5111 MEMORIAL HIGHWAY
TAMPA, FL 33634-7356

EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	10/072,084	TORRES, JOSE V.	
	Examin r	Art Unit	
	T. D. Wessendorf	1639	

-- Th MAILING DATE of this communication appears on the c v r sheet with th c rrespond nc address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 0504*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *14 and 17-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-13 and 15-16 in the 5/4/04 restriction requirement is acknowledged. Also, Applicant's election with traverse of Group I, claims 1-16 in the restriction requirement of 12/15/03 is also acknowledged. The traversal is on the ground(s) that Applicant believes that claims 1 to 31 relate to the same inventive concept, regardless of the differences in the claim preambles. Specifically, claims 1 to 16 relate to a process for forming a peptide mixture. The peptide mixture itself, although claimed in an independent format, is the subject of claims 17 to 19, and compositions containing this mixture is recited in dependent claims 20 to 23. Additionally, dependent claims 24 and 25 relate back to the peptide mixture. Clearly, these claims have a common inventive theme, and that is the origins from which the peptide mixture arises (as recited in claims 1 to 16). Claims 26 and 27 also depend from claim 1, even though other components of a kit are recited. Process claims 28 to 30. also recite the peptide mixture of claim would thus clearly be considered within the bounds of the common inventive concept. Claim 31 relates back to claim 30, and thus contains all the limitations of that claim. Although the Applicant

elects Group I claims, is nevertheless believed that all claims 1 to 31 relate to a common inventive concept. Under the Manual of Patent Examining Procedure (MPEP) Section 803 - Restriction - When Proper: Under the statute, an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents, and they are either independent (MPEP 5806.04 5806.04(j)) or distinct (MPEP 5806.05 5806.05(i)). Accordingly, it is submitted that all claims are based on a common concept, that they are so closely related that a search would not be unduly burdensome, that they should be examined the same application as part of the same invention. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions. This is not found persuasive because as recognized by applicants under the cited MPEP section, restriction of inventions has been made since the inventions are not only distinct. Each of the inventions are also independent and can support different patentable subject matter for the various reasons provided at page 3 of the 12/15/03 restriction requirement. Thus, restriction was made not merely due to the differences in the preambles or because there is a common concept. Because each of

the inventions is distinct and independent, examination would indeed by unduly extensive. The search is not only limited to Patents searches but literature searches as well. These searches are not co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14 and 17-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Applicant's election of the HIV as the pathogen is also acknowledged. Applicant states that the invention defined by Group I claims should not be considered as limited to any specific pathogen as the method is clearly applicable to any number of different pathogens. Applicant understands that the election is made only for the purposes of facilitating prior art searching.

Status of Claims

Claims 1-31 are pending

Claims 14 and 17-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-13 and 15-16 are under examination.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate written description of a process for preparing an immunogenic peptide

mixture of the claimed genus. There is no structural formula to enable the making of a peptide mixture. Given no description as to the structure of an immunogenic epitope of a pathogen it is not apparent from the disclosure as to the numerous pathogens that is considered to be a common residue or a variable residue. Furthermore, it is well known in the art that synthesis of a peptide be it a single or mixture of a peptide requires structure of a peptide to enable its synthesis i.e., a chain lengthening of the amino residues present in a peptide. Because a pathogen undergoes variability or mutations, strain by strain variability hence, it is not apparent just which will be considered a common residue region or a variable region. As a pathogen can comprise numerous immunogenic epitopes, not defining the structure does not relate to any description of the method. A "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Col, 43 USPQ 2d 1398, 1405(1997), quoting Fiers V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993) [The claims at issued in University of California v. Eli Lilly

defined the invention by function of the claimed DNA (encoding insulin)].In Amgen v. Chugai, the court explained that:

> A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, . . . because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Except for the generalizations made in the specification, there is an inadequate description a pathogen as to the common region or variable region that can be encompassed by the different thousands of pathogens. There is no general description as to the immunogenic epitopes that a pathogen can contain or if there are several different epitopes where the limiting epitopic regions can be made such that the common and variable regions would be equally presented. Furthermore, it is not apparent just what the threshold frequency determinable for each of the different pathogens. Pathogens cover innumerable bacteria, viral, fungal and etc. types of pathogens.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 and 15-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Anderson et al (Vaccine, 1994).

Anderson discloses at page 736, Materials and methods Heading, a method of making an immunogenic peptide mixture comprising obtaining from sequence databases or from various publications in vivo isolates of SIV. The amino acids occurring for each position in an epitope were determined from the sequence information. See Table 1 as to the amino acid

composition of a HEC based on a hypervariable SIV epitope with the threshold frequency of 15% as found on the variable region. During solid phase peptide synthesis, amino acid is added to resin beads in each cycle to form a growing peptide chain. The figures show the percentage of each amino acid that was added at each cycle to the growing peptide chain. The percentages of amino acid added at each cycle were based on the frequency at which they were found at a specific location, based on in vivo sequence data. The specific method steps of Anderson employing specifically SIV peptide mixtures anticipate the broad claimed method steps using peptide of undefined structures. Furthermore, the claimed method of calculating the frequency as rounded to the nearest 25% would appear to be inherent to the method of Anderson or if not would have been obvious to calculate from a given pathogen variability. [Because the claims are subject to several interpretations hence, the rejection under 102/103 is proper. See MPEP 2116.01.]

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
January 7, 2005